

Notice of Allowability	Application No.	Applicant(s)	
	09/779,334	SJOEHOLM ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 15, 2005.
2. ☒ The allowed claim(s) is/are 28-49.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>1/6/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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DETAILED ACTION

Claims 28-49 are pending. Claims 1-27 were canceled by Amendment un 37 C.F.R.

1.116, dated December 15, 2005.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Elias Lambiris on January 6, 2005.

The application has been amended as follows:

Claim 28 (Currently Amended). An animal feed additive comprising (a) at least one purified acid-stable subtilisin ~~protease~~ and (b) one or more fat soluble vitamins and/or water soluble vitamins, and (c) one or more trace minerals, ~~wherein the protease is a subtilisin~~, wherein the acid stability of the ~~protease~~ subtilisin means that the activity of the pure subtilisin ~~protease~~, in a dilution corresponding to $A_{280}=1.0$, is at least 40% of the reference activity of the subtilisin ~~protease~~, wherein the activity of the ~~protease~~ subtilisin is measured after two hours incubation at a temperature of 37°C in a buffer of 100 mM succinic acid, 100 mM HEPES, 100 mM CHES, 100 mM CABS, 1 mM CaCl_2 , 150 M KCl, and 0.01% Triton X-100 (pH 3.5), and wherein the reference activity is measured after two hours incubation at a temperature of 5°C in the same buffer but adjusted to pH 9.0, wherein the activity and reference activity are measured after these incubations, at 25°C in Suc-AAPF-pNA (pH 9.0).

Claim 29 (Currently Amended). The animal feed additive of claim 28, wherein the activity of the pure ~~protease~~ subtilisin is at least 45% of the reference activity of the subtilisin ~~protease~~.

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Claim 30 (Currently Amended). The animal feed additive of claim 29, wherein the activity of the ~~protease~~ subtilisin is at least 50% of the reference activity.

Claim 31 (Currently Amended). The animal feed additive of claim 30, wherein the activity of the ~~protease~~ subtilisin is at least 60% of the reference activity.

Claim 32 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin has a pH optimum in the range of 6.0-11.0.

Claim 33 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is a *Bacillus sp.*, NCIMB 40484 subtilisin ~~protease~~.

Claim 34 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is a *Bacillus alcalophilus* NCIMB 10438 subtilisin ~~protease~~.

Claim 35 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is a *Fusarium oxysporum* IFO 4471 subtilisin ~~protease~~.

Claim 36 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is a *Paecilomyces lilacinus* CBS 102449 subtilisin ~~protease~~.

Claim 37 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is an *Acremonium chrysogenum* ATCC 48272 subtilisin ~~protease~~.

Claim 38 (Currently Amended). The animal feed additive of claim 28, wherein the ~~protease~~ subtilisin is an *Acremonium kiliense* ATCC 20338 subtilisin ~~protease~~.

Claim 39 (Currently Amended). The animal feed additive of claim 28, wherein the amount of the purified ~~protease~~ subtilisin corresponds to 0.01-200 mg ~~protease~~ subtilisin protein per kg feed.

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Claim 40. An animal feed additive of claim 28, for addition to an animal feed having a crude protein content of 50-800 g/kg.

Claim 41. The animal feed additive of claim 28, which further comprises at least one enzyme selected from the group consisting of phytase, xylanase, galactanase, and beta-glucanase.

Claim 42. A method for the improving the nutritional value of a vegetable protein or protein source, comprising adding an animal feed additive of claim 28 to the vegetable protein or protein source.

Claim 43. The method of claim 42, wherein the vegetable protein comprises soybean.

Claim 44 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is a *Bacillus sp.*, NCIMB 40484 subtilisin ~~protease~~.

Claim 45 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is a *Bacillus alcalophilus*, NCIMB 10438 subtilisin ~~protease~~.

Claim 46 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is a *Fusarium oxysporum*, IFO 4471 subtilisin ~~protease~~.

Claim 47 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is a *Paecilomyces lilacinus*, CBS 102449 subtilisin ~~protease~~.

Claim 48 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is an *Acremonium chrysogenum*, ATCC 48272 subtilisin ~~protease~~.

Claim 49 (Currently Amended). The method of claim 42, wherein the ~~protease~~ subtilisin is an *Acremonium kiliense*, ATCC 20338 subtilisin ~~protease~~.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: Applicants' Declaration Under 37 C.F.R. 1.132 and the arguments presented in the Amendment, dated December 15, 2004 obviate the 35 USC 102 rejections by Hiller (4,239,750), Hiller (4,225,584), Hiller (4,218,437) and Lehmann (4,062,732), as it is now demonstrated that they fail to disclose the *Bacillus subtilis* and *Bacillus licheniformis* subtilins are acid-stable according to the definition of the instant claims. Additionally, the present invention comprises independent claim 28, this claim discloses acid-stable subtilins according to a specific definition of the instant claims. This feature distinguishes Applicants' invention over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer I. Harle
Examiner
Art Unit 1654

January 10, 2005

A handwritten signature in black ink, reading "Bruce Campell". The signature is written in a cursive, flowing style.

**BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**